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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,054	03/22/2006	Anthony Robert Milnes Coates	Q87779	2651

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,054	COATES, ANTHONY ROBERT MILNES	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-53* is/are rejected.

7)☒ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/06,5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Preliminary Amendment, received 6 May 2005, is acknowledged. Claims 1-28 have been canceled. New claims 29-53 have been added.

2. Claims 29-53 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 1, line 1, the priority statement should include the foreign application; line 12, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01; line 24, "synthesised" should be "synthesized".

Page 2, line 6, "characterised" should be "characterized".

Page 4, line 29, "hybridises" should be "hybridizes".

Page 8, line 9, delete one of the periods following identity ".."

Page 9, lines 17, 21, 25, "Cpn 60.1" should be "cpn 60.1" as first defined, page 2, line 24; line 19, "Mtcpn60.1" should be "Mt cpn 60.1" as first defined, page 2, line 26; line 27, "Mtcpn60.2" should be "Mt cpn 60.2" as first defined, page 2, line 26.

Page 10, line 1, "Cpn 60.2" should be "cpn 60.2"; lines 5, 9, "Cpn 10" should be "cpn 10".

Page 13, line 28, "cpn60.1" should be "cpn 60.1".

Page 12, line 25, "Cpn 60.1, Cpn 60.2 and Cpn 10" should be "cpn 60.1, cpn 60.2 and cpn 10".

Page 14, line 1, "cpn60.1" should be "cpn 60.1"; lines 18, 25, 28, 30, "cpn60.2" should be "cpn 60.2".

Page 15, lines 16, 22, 25, 27, 29, "cpn10" should be "cpn 10".

Page 16, lines 1, 11, 12, "cpn10" should be "cpn 10"; line 14, "Cpn 10" should be "cpn 10".

Page 19, line 1, "lyophilised" should be "lyophilized"; lines 24, 30, "nebuliser" should be "nebulizer"; lines 28, 30, "pressurised" should be "pressurized".

Page 20, line 23, "micronised" should be "micronized".

Page 22, line 1, "Cancer" should be "cancer".

Appropriate correction is required.

Drawings

4. Figure 4 is objected to because the figure lists "CP.01", but there is no such designation in the description of the figure.

5. Figure 5 is objected to because the figure lists "CP.01", but there is no such designation in the description of the figure.

6. Figure 6 is objected to because the figure lists "CP.02", but there is no such designation in the description of the figure.

7. Figure 7 is objected to because the figure lists "CP.02", but there is no such designation in the description of the figure.

8. Figure 8 is objected to because "CPn 10" should be "cpn 10".

9. Figure 9 is objected to because "CPn 10" should be "cpn 10".

10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

11. Claim 34 is objected to because of the following informalities: line 6, "hybridises" should be "hybridizes". Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 31-34 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites that the heat shock polypeptide is "derived" from a bacterium. It is unclear what are the metes and bounds of "derived" because the specification does not defined the term.

14. Claims 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 35 are drawn to sequences "of Figure 1 and/or Figure 2 and/or Figure 3". This is indefinite for two reasons.

First, Figures 1-3 may be amended even though the claims may not be amended. Thus, the actual sequences that are being claimed will vary. It is recommended that the SEQ ID NOs be inserted into the claims.

Second, the recitation that the sequences are "of" the figures is unclear because it is uncertain if the claimed sequences consist of the designated sequences or are subsequences of the designated sequences.

Claims 36-38 are dependent claims, but do not clarify the issues.

15. Claims 39-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 40 recite dependence from claim 29 wherein "the a heat shock polypeptide or a nucleotide molecule" is administered.

The use of "the" for only the peptide renders the claim unclear if the nucleotide molecule is the same as in claim 29 or another "a" nucleotide molecule.

If both the polypeptide and nucleotide molecule are those of claim 29, it is recommended that the wording be "wherein said heat shock polypeptide or said nucleotide molecule".

Claims 41-50 are dependent claims, but do not clarify the issue.

16. Claims 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is drawn to a composition comprising at least one additive "for assisting or augmenting the action"of the nucleotide molecule or polypeptide.

It is unclear what are the metes and bounds of "for assisting or augmenting the action". For example, does the additive augment the pain relief or absorption of the nucleotide or polypeptide into a subject.

17. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the composition is "in a form which provides prolonged or sustained pain relief". It is unclear what structural characteristics are encompassed by such a "form".

18. Claims 34-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for whole heat shock proteins, does not reasonably provide enablement for any/all fragments of said heat shock proteins providing pain relief. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - methods of pain relief utilizing fragments of heat shock proteins or fragments of the nucleic acid sequence encoding said heat shock proteins.

The state of the prior art indicates that heat shock proteins, i.e., chaperonins are known to assist in polypeptide folding (Ranson et al, *Biochem. J.*, 333:233-242, 1998). However, utilizing said chaperonins for pain relief was not known. Thus, there was a lack of predictability in the art that chaperonins could be utilized for pain relief, and any fragments of said chaperonins were also not known to alleviate pain.

The amount of direction or guidance present in the instant specification is insufficient for the scope of the instant claims, i.e., any fragment of any size utilized as pain relief. The only examples in the specification utilized whole cpn 60.1, cpn 60.2 or cpn 10. The specification does not teach which part, if any, of less than the whole sequence can replace the whole molecule and retain all of its pain relief characteristic.

Thus, the quantity of experimentation necessary constitute merely an invitation to experiment with fragments of chaperonins, without a reasonable expectation of success.

19. Claims 29-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for relieving pain utilizing whole heat shock proteins, does not reasonably provide enablement for relieving pain by administration of polynucleotides encoding a heat shock polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - methods of pain relief utilizing nucleotides encoding heat shock proteins.

The state of the prior art indicates that heat shock proteins, i.e., polypeptide chaperonins are known to assist in polypeptide folding (Ranson et al, *Biochem. J.*, 333:233-242, 1998). However, utilizing said chaperonins or their nucleotides for pain relief was not known. Thus, there was a lack of predictability in the art that chaperonins could be utilized for pain relief, and any nucleotides encoding said chaperonins were also not known to alleviate pain.

The amount of direction or guidance present in the instant specification is insufficient for the scope of the instant claims, i.e., administration of nucleotides encoding heat shock polypeptides for pain relief. The only examples in the specification utilized whole cpn 60.1, cpn

60.2 or cpn 10 polypeptides. The specification does not teach that administration of the nucleotides encoding whole cpn 60.1, cpn 60.2 or cpn 10 polypeptides can replace the whole polypeptides and retain all of their pain relief characteristic.

Thus, the quantity of experimentation necessary constitute merely an invitation to experiment with fragments of chaperonins, without a reasonable expectation of success.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 30, 2008

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/534,054	COATES, ANTHONY ROBERT MILNES	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	